

Rec'd PCT/PTO 05 MAY 2005

INTERNATIONAL COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 22 MAR 2005

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Applicant's or agent's file reference FP18697	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International Application No. PCT/AU2003/001556	International Filing Date (day/month/year) 20 November 2003	Priority Date (day/month/year) 20 November 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ G06F 17/60		
Applicant METATHEME PTY LTD et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:
 - I ☒ Basis of the report
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☒ Certain observations on the international application

Date of submission of the demand 17 June 2004	Date of completion of the report 4 March 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer DALE SIVER Telephone No. (02) 6283 2196

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☒ the description, pages 1-19 as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☒ the claims, pages 20-28 as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- ☒ the drawings, Figure 1-7 (20 November 2003), 8/11 to 11/11 (8 March 2004) as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-45	YES
	Claims	NO
Inventive step (IS)	Claims 1-31,33-36,38-45	YES
	Claims 32,37	NO
Industrial applicability (IA)	Claims 1-45	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

- D1 FELTER S. et al. "The Inexact Science of Risk Assessment (and Implications for Risk Management)" Human and Ecological Risk Assessment: 1998 Vol. 4, No.2 pp 245-251
- D2 US 6353767 B1 (WAKEMAN et al.) 5 March 2002
- D3 US 6223143 B1 (WEINSTOCK et al.) 24 April 2001
- D4 US 5999918 A (WILLIAMS et al.) 7 December 1999
- D5 WO 1998/013776 A1 (RCO SOFTWARE LIMITED) 2 April 1998
- D6 DECISION of Comptroller General of the United States ; **Resource Applications, Inc.** protest File B-274943.3 March 5, 1997

Novelty (N)

The claims are novel in light of the above documents.

Inventive step (IS)

D1 discloses the nature of risk assessment, with particular reference to risk estimates published by the EPA (Environmental Protection Authority in the U.S.). FELTER et al. teaches associating a "subjective level of confidence" with the risk estimate. The figure on page 249 shows a table of factors affecting the precision of the estimate, including a confidence factor (eg. confidence in reference dose RfDs). Given the teachings of FELTER et al. the person skilled in the art of performing risk calculations would implement the features defined in at least claims 32 and 37 without exercising any inventive faculties.

In certain states D6 can be considered persuasive evidence that LOCAR was common general knowledge (see Box VIII). Claims 32 and 37 lack an inventive step when D1 is combined with D6.

It was found in the Resource Application decision that "There is nothing inherently objectionable in an agency's decision to develop a consensus rating." Furthermore the ratio of the decision strongly implies that using LOCAR was an uncontested form of the consensus rating. D1 teaches to use "a range of weightings" (see page 247 of D1) as defined in D1. D1 does not explicitly describe the LOCAR procedure however it appears to be routine procedure at the EPA. Therefore a person skilled in the art of risk assessment with the teachings of D1 available, would immediately compare the LOCAR weightings to a "range of weightings" associated with the factors in order to determine the level of confidence in the risk assessment. It was found in the decision that using LOCAR (level of confidence assessment rating) was a reasonable risk assessment procedure.

Claims 32 and 37 lack an inventive step when D1 is considered in light of common general knowledge or combined with D6.

Industrial applicability (IA)

The application has an industrial application (eg. risk assessment calculations).

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. For an in depth discussion of the LOCAR technique see <http://www.wifcon.com/analquest2.htm>

This web site indicates that the LOCAR technique has been used by the US Navy ostensibly from 1994 onwards. The Environmental Protection Agency clearly used it at least by 1997 (obvious from the Resource Applications Decision).

LOCAR was an accepted US Government practice for level of confidence assessment rating.